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Boehringer  
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TO: USPTO, Mail Stop Amendment  
Thomas Sweeny HEARD

Boehringer Ingelheim  
Corporation

DATE: January 26, 2005

Fax Number: (571) 273-8300  
Phone Number: (571) 272-2064

Total Number of pages: 25 (including cover sheet)

RE: Information Disclosure Transmittal  
Serial Number: 10/791,318  
Confirmation Number: 1817  
Filing Date: 03/02/2004  
First Inventor: BAILEY, M.D. et al.  
Attorney Docket Number: 13/112

Philip I. Datlow  
Telephone (203) 798-4542  
Telefax (203) 798-4408  
E-Mail [pdatl@rdg.boehringer-ingelheim.com](mailto:pdatl@rdg.boehringer-ingelheim.com)


900 Ridgebury Rd/P.O. Box 368  
Ridgefield, CT 06877-0368

Dear Sir:

Please find transmitted herewith Transmittal Letter for Information Disclosure Statement, in triplicate, Information Disclosure Statement by Applicant (Form 1449 A/B) and a copy of the Non Patent Literature Document listed (8 pages) and The International Search Report; PCT/CA2004/000319 (5 pages) which are to be recorded in the United States Patent and Trademark Office.

The Commissioner is hereby authorized to charge or credit any fee which may be required to Deposit Account No. 02-2955.

Respectfully Submitted,

  
Philip I. Datlow  
Reg. No. 41,482

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I hereby certify that this correspondence is being  
facsimile transmitted to the United States Patent  
and Trademark Office to Fax No. (571) 273-8300  
on January 26, 2005

  
Philip I. Datlow, Reg. No. 41,482

JAN 26 2005

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of : BAILEY, M. D. et al. ) Art Unit: 1654  
U.S. Appln. No. : 10/791,318 ) Examiner: Thomas Sweeny HEARD  
Confirmation No. : 1817  
U.S. Filing Date : 03/02/2004  
Title of Invention : Hepatitis C Inhibitor Peptide Analogs  
Attny. Docket No. : 13/112

Mail Stop Amendment  
Commissioner for Patents  
P. O. Box 1450  
Alexandria, VA 22313-1450

January 26, 2005

## TRANSMITTAL LETTER FOR INFORMATION DISCLOSURE STATEMENT

Sir:

In accordance with the duty of disclosure under 37 C.F.R. § 1.56, Applicant hereby notifies the U.S. Patent and Trademark Office of the documents listed herein and on the attached PTO-1449 form and which the Examiner may deem relevant to patentability of the claims of the above-identified application. Copies of the citations listed on the PTO-1449 form are filed in US Application No. 10/791,987, filed on 03/03/2004, LLINAS-BRUNET, Montse (Attorney Docket No. 13/113).

It should be noted that two (2) specific references; WO 00/09543A2 and NAPS and JOHNS: "Optically active mono-substituted succinic acids and derivatives"; Journal of American Chemical Society, vol. 62, 1940, pages 2450-2457, that are listed in the Information Disclosure Statement have been cited in the International Search Report (ISR) for PCT/CA2004/000319, which corresponds to the present US application. A copy of that ISR is enclosed herewith.

☒ 1.97(b). This Statement is being filed: i) within three (3) months of the filing date of a national application other than a continued prosecution application under 33 C.F.R. §1.53 (d); ii) within three (3) months of the date of entry of the national stage as set forth in 37 C.F.R. §1.491 in an international application; iii) before the mailing of a first Office action on the merits; or iv) before the mailing of a first Office action after the filing of a request for continued examination under 37 C.F.R. §1.114.

☐ 1.97(c). This Statement is being filed after the time period specified in 37 C.F.R. §1.97(b), but before the mailing date of: i) a final action under 37 C.F.R. §1.113, ii) a notice of allowance under 37 C.F.R. §1.311, or iii) an action that otherwise closes prosecution in the application. This Statement is being accompanied by:

1 of 3


- ☐ A statement as specified in 37 C.F.R. §1.97(e) [see below]; or
- ☐ The fee set forth in 37 C.F.R. §1.17(p).
- ☐ The Commissioner is hereby authorized to charge payment of the \$180.00 fee set forth in 37 C.F.R. §1.17(p) to Deposit Account No. 02-2955.
- ☐ 1.97(d). This Statement is being filed after the period specified in 37 C.F.R. §1.97(c) but on or before payment of the issue fee. This Statement is accompanied by a statement as specified in 37 C.F.R. §1.97(e) [see below] and the fee set forth in 37 C.F.R. §1.17(p).
- ☐ 1.97(e).
- ☐ Each item of information contained in the instant information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three (3) months prior to the filing of the instant information disclosure statement; or
- ☐ No item of information contained in the instant information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing this certification after making reasonable inquiry, no item of information contained in the instant information disclosure statement was known to any individual designated in 37 C.F.R. §1.56(c) more than three (3) months prior to the filing of the instant information disclosure statement.
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☐ 1.704(d). Each item of information contained in the accompanying information disclosure statement was cited in a communication from a foreign patent office in a counterpart application, which communication was not received by any individual designated in section 1.56(c) more than thirty (30) days prior to the filing of the accompanying information disclosure statement.

☒ The Commissioner is hereby authorized to charge payment of any additional filing fees required under 37 C.F.R. §1.16 and any patent application processing fees under 37 C.F.R. §1.17, or credit any overpayment of same, to Deposit Account No. 02-2955.


Triplicate copies of this form are enclosed.

Respectfully submitted,

  
Philip I. Datlow  
Attorney for Applicant(s)  
Reg. No. 41,482

Patent Department  
Boehringer Ingelheim Corp.  
900 Ridgebury Road, P.O. Box 368  
Ridgefield, CT 06877  
Tel: (203) 798-4542

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Philip I. Datlow, Reg. No. 41,482

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## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of : BAILEY, M. D. et al. ) Art Unit: 1654  
U.S. Appln. No. : 10/791,318 ) Examiner: Thomas Sweeny HEARD  
Confirmation No. : 1817  
U.S. Filing Date : 03/02/2004  
Title of Invention : Hepatitis C Inhibitor Peptide Analogs  
Attny. Docket No. : 13/112

Mail Stop Amendment  
Commissioner for Patents  
P. O. Box 1450  
Alexandria, VA 22313-1450

January 26, 2005

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In accordance with the duty of disclosure under 37 C.F.R. § 1.56, Applicant hereby notifies the U.S. Patent and Trademark Office of the documents listed herein and on the attached PTO-1449 form and which the Examiner may deem relevant to patentability of the claims of the above-identified application. Copies of the citations listed on the PTO-1449 form are filed in US Application No. 10/791,987, filed on 03/03/2004, LLINAS-BRUNET, Montse (Attorney Docket No. 13/113).

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1 of 3

DISCLOSURE


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- ☐ No item of information contained in the instant information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing this certification after making reasonable inquiry, no item of information contained in the instant information disclosure statement was known to any individual designated in 37 C.F.R. §1.56(c) more than three (3) months prior to the filing of the instant information disclosure statement.
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☐ 1.704(d). Each item of information contained in the accompanying information disclosure statement was cited in a communication from a foreign patent office in a counterpart application, which communication was not received by any individual designated in section 1.56(c) more than thirty (30) days prior to the filing of the accompanying information disclosure statement.


☒ The Commissioner is hereby authorized to charge payment of any additional filing fees required under 37 C.F.R. §1.16 and any patent application processing fees under 37 C.F.R. §1.17, or credit any overpayment of same, to Deposit Account No. 02-2955.

Triplicate copies of this form are enclosed.

Respectfully submitted,

  
Philip I. Datlow  
Attorney for Applicant(s)  
Reg. No. 41,482

Patent Department  
Boehringer Ingelheim Corp.  
900 Ridgebury Road, P.O. Box 368  
Ridgefield, CT 06877  
Tel: (203) 798-4542

<p>Certificate of Transmission under 37 CFR 1.8 I hereby certify that this correspondence is being facsimile transmitted to the United States Patent and Trademark Office to Fax No. (571) 273-8300 on January 26, 2005</p> <p> Philip I. Datlow, Reg. No. 41,482</p>
---

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Application of : BAILEY, M. D. et al. ) Art Unit: 1654  
U.S. Appln. No. : 10/791,318 ) Examiner: Thomas Sweeny HEARD  
Confirmation No. : 1817  
U.S. Filing Date : 03/02/2004  
Title of Invention : Hepatitis C Inhibitor Peptide Analogs  
Attny. Docket No.: 13/112

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TRIPPLICA




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(571) 273-8300 on January 26, 2005

  
Philip I. Datlow, Reg. No. 41,482

TRIPPLICATE

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Substitute for form 1448A/PTO

# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 2

Approved for use through 07/31/2008. OMB 0651-0031  
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE  
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Complete if Known

**Complete If Known**

Application Number	10/791,318
Filing Date	03/02/2004
First Named Inventor	Murray D. BAILEY et al.
Art Unit	1854
Examiner Name	Thomas Sweeny HEARD
Attorney Docket Number	13/112

[illegible]

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	7 <sup>6</sup>
		Country Code <sup>2</sup> Number <sup>3</sup> Kind Code <sup>4</sup> (if known)				
		WO 99/07733 A2	02/18/1999	BI (Canada) Ltd.		
		WO 00/09543 A2	02/24/2000	BI (Canada) Ltd.		
		WO 00/09558 A1	02/24/2000	BI (Canada) Ltd.		
Examiner						

Examiner Signature		Date Considered	
<p>*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Drawings should be considered. Include copy of this form with pertinent references.</p>			

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 809. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 See Kind Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.18 if possible. 6 Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

*If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.*



## PATENT COOPERATION TREATY

PATENT DEPARTMENT

DEC 17 2004

From the INTERNATIONAL SEARCHING AUTHORITY

PCT

To:  
BOEHRINGER INGELHEIM (CANADA) LTD.  
2100 Cunard Street  
Laval, Quebec H7S 2G5  
CANADA

## INVITATION TO PAY ADDITIONAL FEES

(PCT Article 17(3)(a) and Rule 40.1)

REGISTERED MAIL

Date of mailing (day/month/year)	29/11/2004
Applicant's or agent's file reference 13-112WO	PAYMENT DUE within 30 <del>100000</del> days from the above date of mailing
International application No. PCT/CA2004/000319	International filing date (day/month/year) 02/03/2004
Applicant BOEHRINGER INGELHEIM INTERNATIONAL GMBH	

## 1. This International Searching Authority

- (i) considers that there are 2 (number of) inventions claimed in the international application covered by the claims indicated ~~below~~ on the extra sheet;

and it considers that the international application does not comply with the requirements of unity of invention (Rules 13.1, 13.2 and 13.3) for the reasons indicated ~~below~~ on the extra sheet:

- (ii) ☒ has carried out a partial international search (see Annex) ☐ will establish the international search report on those parts of the international application which relate to the invention first mentioned in claims Nos.:  
see annex

- (iii) will establish the international search report on the other parts of the international application only if, and to the extent to which, additional fees are paid


## 2. The applicant is hereby invited, within the time limit indicated above, to pay the amount indicated below:

EUR 1.550.00 x 1 = EUR 1.550.00  
Fee per additional invention      number of additional inventions      total amount of additional fees

Or, \_\_\_\_\_ x \_\_\_\_\_ = \_\_\_\_\_

The applicant is informed that, according to Rule 40.2(c), the payment of any additional fee may be made under protest, i.e., a reasoned statement to the effect that the international application complies with the requirement of unity of invention or that the amount of the required additional fee is excessive.

3. ☒ Claim(s) Nos. see annex have been found to be unsearchable under Article 17(2)(b) because of defects under Article 17(2)(a) and therefore have not been included with any invention.

Name and mailing address of the International Searching Authority  
 European Patent Office, P.B. 5818 Patentlaan 2  
NL-2280 HV Rijswijk  
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,  
Fax: (+31-70) 340-3016

Authorized officer

Catriona Cleere

Form PCT/ISA/206 (July 1992)

**Annex to Form PCT/ISA/206  
COMMUNICATION RELATING TO THE RESULTS  
OF THE PARTIAL INTERNATIONAL SEARCH**

International Application No

PCT/CA2004/000319

1. The present communication is an Annex to the invitation to pay additional fees (Form PCT/ISA/206). It shows the results of the international search established on the parts of the international application which relate to the invention first mentioned in claims Nos.:
2. This communication is not the international search report which will be established according to Article 18 and Rule 43.   
see 'Invitation to pay additional fees'
3. If the applicant does not pay any additional search fees, the information appearing in this communication will be considered as the result of the international search and will be included as such in the international search report.
4. If the applicant pays additional fees, the international search report will contain both the information appearing in this communication and the results of the international search on other parts of the international application for which such fees will have been paid.

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 00/09543 A (BOEHRINGER INGELHEIM CA LTD ; GOUDREAU NATHALIE (CA); GHIRO ELISE (CA)) 24 February 2000 (2000-02-24) cited in the application Abstract; p. 21, formula on the right; compounds 333, 334, 616, 621, 628-630, 707, 709, 711, 713, 714, 717, 719, 722, 723, 728, 732 and 733.	1-40
A	NAPS AND JOHNS: "Optically active mono-substituted succinic acids and derivatives" JOURNAL OF THE AMERICAN CHEMICAL SOCIETY, vol. 62, 1940, pages 2450-2457, XP002290591 "N-Methylsuccinamic acid" at p. 2454	1-40

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

## \* Special categories of cited documents:

- \*A\* document defining the general state of the art which is not considered to be of particular relevance
- \*E\* earlier document but published on or after the international filing date
- \*L\* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- \*O\* document referring to an oral disclosure, use, exhibition or other means
- \*P\* document published prior to the international filing date but later than the priority date claimed

\*T\* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

\*X\* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

\*Y\* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

\*S\* document member of the same patent family

Form PCT/ISA/206 (Annex, first sheet) (July 1992; revised January 2004)

**Patent Family Annex**  
Information on patent family members

International Application No

PCT/CA2004/000319

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 0009543	A	24-02-2000	
		AU 769738 B2	05-02-2004
		AU 5273199 A	06-03-2000
		BG 105232 A	30-11-2001
		BR 9913646 A	05-06-2001
		CA 2338946 A1	24-02-2000
		CA 2445938 A1	24-02-2000
		WO 0009543 A2	24-02-2000
		CN 1323316 T	21-11-2001
		CZ 20010516 A3	15-08-2001
		EA 3906 B1	30-10-2003
		EE 200100081 A	15-08-2002
		EP 1105413 A2	13-06-2001
		HR 20010102 A1	28-02-2002
		HU 0105144 A2	29-04-2002
		ID 27839 A	26-04-2001
		JP 2002522554 T	23-07-2002
		NO 20010683 A	02-04-2001
		NZ 510396 A	27-02-2004
		PL 346626 A1	25-02-2002
		SK 2062001 A3	08-10-2001
		TR 200100432 T2	21-09-2001
		TR 200200129 T2	21-06-2002
		US 6534523 B1	18-03-2003
		US 6323180 B1	27-11-2001
		US 6268207 B1	31-07-2001
		US 6329379 B1	11-12-2001
		US 6329417 B1	11-12-2001
		US 2002016442 A1	07-02-2002
		US 2002037998 A1	28-03-2002

From PCT/CA/2004/000319 (Patent Family Annex) (Date 1999: revised, 2004: revised)

## INVITATION TO PAY ADDITIONAL FEES

International application No.

PCT/CA2004/000319

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

## 1. claims: 1-40

Compounds of formula I, their compositions, medical uses and method of preparation.

## 2. claims: 41-47

Compounds of formula II and uses.

The application lacks unity in the sense of Rule 13 PCT.

Each of inventions 1 and 2 is characterised by an individual "special technical feature"; there is no technical interrelation between the said two inventions.

Rule 13.1 PCT demands that the "international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept". Rule 13.2 PCT demands that Rule 13.1 PCT shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

In the present case Rule 13.2 PCT should be considered to be met when the different inventions share a common chemical structure which constitutes a structurally distinctive portion in view of the existing prior art.

Inventions 1 and 2 have in common the succinamic structure of formula II.

However, this common feature could not be considered as the special technical feature defining a contribution over the prior art, since compounds of formula II are already known from the prior art (Naps and Johns (1940) J. Amer. Chem. Soc. 62, 2450-2457, see "N-methylsuccinamic acids" at p. 2454).

In the absence of a further technical feature which could serve as same or corresponding technical feature in the sense of Rule 13.2 PCT, there is lack of unity between inventions 1 and 2.



International Application No. **PCT/CA2004/000319****FURTHER INFORMATION CONTINUED FROM PCT/SA/ 206**

Continuation of Box 3.

Although claims 31-37 and 39 are directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the compound/composition.

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Further defect(s) under Article 17(2)(a):

Continuation of Box 3.

Claim(s) not searched:  
31-37, 39, 48

Claims 31-37 and 39: Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy

Claim 48: Rule 39.1(iii) PCT - Scheme, rules and method for doing business